

### **REMARKS**

Claims 61-71 remain pending in the application. Applicants have herein amended Claims 61-65 and 70-71, and have added new Claims 72-78 so as to more clearly define the subject matter claimed therein. In that the amended Claims 61-65 and 70-71, and newly added Claims 72-78 do not introduce new matter and are supported in the specification as originally filed, their entry is respectfully requested. Specification support for amended Claims 61-65 and 70-71, and newly added Claims 72-78 can be found at least as follows: page 3, lines 15-38; page 4, lines 1-9 and 24-38; page 5, lines 1-38; page 6, lines 1-11; page 7, lines 9-27; page 8, lines 22-29; page 17, lines 9-34; page 18, lines 1-27; page 20, lines 3-18; page 27, lines 28-34; page 28, lines 1-34; pages 73-75, EXAMPLE 2; pages 82-83, EXAMPLE 10; page 85, EXAMPLE 12; pages 88-91, EXAMPLE 16; and the claims as originally filed.

#### **Provisional Double Patenting Rejections:**

Claims 62-67 stand provisionally rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of Claims 54, 76, 80, 81, 85 and 86 of copending Application No. 09/311,832. Without necessarily agreeing with the propriety of the outstanding rejection, Applicants respectfully request that this rejection be held in abeyance until such time as there is an indication from the Examiner of otherwise allowable subject matter herein, wherein Applicant will cancel or amend the conflicting claims so they are no longer coextensive in scope.

#### **Objections and Rejections under 35 U.S.C. §112, Second Paragraph**

Claims 70 and 71 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being

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indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have herein amended Claim 70 to clarify that said host cell of Claim 69 is an insect cell comprising a Baculovirus expression vector, thereby obviating the rejection thereof. In addition, Claim 71 has been amended herein to identify a polypeptide having at least 80% amino acid sequence identity to SEQ ID NO:3, thereby obviating the rejection.

**Objections and Rejections under 35 U.S.C. §112, First Paragraph**

Claims 61 and dependent Claims 68-71 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner alleges that the specification provides no guidance as to how the skilled artisan could use an inactive polypeptide variant of SEQ ID NO:3, encoded by the claimed nucleic acid variants, as no functional limitation is associated with the variants in the claims. In addition, the Examiner states that Claims 62-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Without necessarily agreeing with the propriety of the rejections, Applicants have herein amended Claims 61-65 and added new Claims 72-78. Applicants will respond to the rejection as if it would apply to the amended and newly added claims submitted herewith. Applicants respectfully traverse the rejections.

The Examiner has stated that the specification allegedly provides no guidance as to how the skilled artisan could use an inactive variant of SEQ ID:3, as no functional limitation is associated with the variants. Without necessarily agreeing with the propriety of the rejection, Applicants have herein amended the claims directed to variants to include the functional limitation "wherein said isolated nucleic acid molecule

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encodes a polypeptide capable of inducing the production of TNF- $\alpha$  in human leukemia monocytic THP-1 cells". Thus, the claims as amended are directed to biologically active variants. In so much as the specification clearly describes how to make and how to use active variants, Applicants respectfully submit that the presently claimed invention is fully supported and described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection under 35 U.S.C. §112, first paragraph.

In light of the above amendments and remarks, Applicants believe that this application is now in condition for immediate allowance and respectfully request that the outstanding rejections be withdrawn and this case passed to issue.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims**

New Claims 72-81 have been added.

Claim 61 has been amended as follows:

61. (~~New~~Amended) An isolated nucleic acid molecule which comprises DNA having at least 80% nucleic acid sequence identity to:
- (a) a nucleotide sequence that encodes ~~a polypeptide consisting of~~ amino acid residues 1 to 197 of ~~the amino acid sequence shown as~~ SEQ ID NO:3,
  - (b) a nucleotide sequence that encodes ~~a polypeptide consisting of~~ amino acid residues 19 to 197 of ~~the amino acid sequence shown as~~ SEQ ID NO:3,
  - (c) the nucleotide sequence from position 50 to 640 of ~~the nucleic acid sequence shown as~~ SEQ ID NO:4,
  - (d) the nucleotide sequence from position 104 to 640 of ~~the nucleic acid sequence shown as~~ SEQ ID NO:4,
  - (e) the full-length coding sequence of the cDNA deposited under ATCC accession number 203552, or
  - (f) the full-length coding sequence of the cDNA deposited under ATCC accession number 203552 lacking its associated signal peptide encoding region; wherein said isolated nucleic acid molecule encodes a polypeptide capable of inducing the production of TNF- $\alpha$  in human leukemia monocytic THP-1 cells.

Claim 62 has been amended as follows:

62. (~~New~~Amended) The isolated nucleic acid molecule of Claim 61 which comprises DNA encoding ~~a polypeptide consisting of~~ amino acid residues 1 to 197 of ~~the amino acid sequence shown as~~ SEQ ID NO:3.

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Claim 63 has been amended as follows:

63. (New Amended) The isolated nucleic acid molecule of Claim 61 which comprises DNA encoding a polypeptide consisting of amino acid residues 19 to 197 of the amino acid sequence shown as SEQ ID NO:3.

Claim 64 has been amended as follows:

64. (New Amended) The isolated nucleic acid molecule of Claim 61 which comprises the nucleotide sequence from position 50 to 640 of the nucleic acid sequence shown as SEQ ID NO:4.

Claim 65 has been amended as follows:

65. (New Amended) The isolated nucleic acid molecule of Claim 61 which comprises the nucleotide sequence from position 104 to 640 of the nucleic acid sequence shown as SEQ ID NO:4.

Claim 70 has been amended as follows:

70. (New Amended) The host cell of Claim 69 which is a CHO cell, an *E. coli*, a yeast cell or a ~~Baculovirus-infected insect cell~~ an insect cell comprising a Baculovirus expression vector.

Claim 71 has been amended as follows:

71. (New Amended) A process for producing a polypeptide ~~comprising~~ having at least 80% amino acid sequence identity to SEQ ID NO:3, wherein said process comprises culturing the host cell of Claim 69 under conditions suitable for expression of said polypeptide and recovering said polypeptide from the cell culture.